UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC., **Plaintiff,** **v.** **NOVITIUM PHARMA, LLC,** **Defendant.**	**Case No. 22–cv–05860–ES–ESK** **OPINION AND ORDER**

KIEL, U.S.M.J.

THIS MATTER having come before the Court on: (1) the motion by defendant Novitium Pharma, LLC (Novitium) and proposed intervenor-defendant Bionpharma Inc. (Bionpharma) to transfer the case to the United States District Court for the District of Delaware (Transfer Motion); and (2) Bionpharma's separate motion to intervene in the case (Intervene Motion) (ECF Nos. 8, 10); and plaintiff Azurity Pharmaceuticals, Inc. (Azurity) having filed oppositions to the Transfer Motion and the Intervene Motion (ECF Nos. 25, 26, 27); and Novitium and Bionpharma having filed replies in further support of the Transfer Motion and the Intervene Motion (ECF No. 34, 35); and the Court finding:

1. Azurity, a Delaware corporation with a Massachusetts principal place of business, holds a family of patents encompassing a medication known as enalapril, including United States Patent Nos. 11,040,023 ('023 patent) and 11,141,405 ('405 patent). (ECF No. 1 ¶¶1, 2, 12–21.) The '023 patent and the '405 patent do not expire until March 2036. (*Id.* ¶31.) Enalapril "is approved for hypertension in children one month of age and older and is also indicated to treat hypertension, heart failure, and asymptomatic left ventricular dysfunction in adults." (*Id.* ¶11.)

2. In June 2021, Azurity brought an action against Bionpharma, a Delaware corporation with a New Jersey principal place of business, in the District of New Jersey. *See Azurity Pharms., Inc. v. Bionpharma Inc.*, D.N.J. Case No. 21-12870, ECF No. 1. In that case, Azurity alleged that Bionpharma infringed the '023 patent by submitting the Abbreviated New Drug Application (ANDA) No. 212408 to the United States Food and Drug Administration (FDA)

for approval to manufacture and market a generic version of enalapril (First Bionpharma Case). *Id.*

3. On September 10, 2021, District Judge Michael A. Shipp transferred the First Bionpharma Case to the District of Delaware, as: (a) several related cases addressing the alleged infringement of members of the enalapril patent family wherein Azurity was the plaintiff were pending there since 2018; (b) some of those related cases were brought against Bionpharma, and the District of Delaware had already held bench trials, and had issued findings of fact and conclusions of law; (c) the District of Delaware judiciary would be familiar with the enalapril patent family and the issues therein; and (d) the potential preclusive effect of the District of Delaware's holdings upon the determinations to be made in the First Bionpharma Case would be best addressed by the District of Delaware judiciary. *Id.* ECF Nos. 56, 57 (order and underlying sealed opinion). The First Bionpharma Case is now being actively litigated in the District of Delaware. *See Azurity Pharms., Inc. v. Bionpharma Inc.*, D. Del. Case No. 21-01286.

4. In October 2021, one month after the First Bionpharma Case was transferred, Azurity brought a new action against Bionpharma in the District of Delaware, alleging that Bionpharma also infringed the '405 patent by submitting ANDA No. 212408 to the FDA (Second Bionpharma Case). *See Azurity Pharms., Inc. v. Bionpharma Inc.*, D. Del. Case No. 21-01455, ECF No. 1. Since at least January 2022, the District of Delaware has "coordinat[ed]" the oversight of the First and Second Bionpharma Cases for the purposes of discovery and case management. *See* D. Del. Case No. 21-01286, ECF No. 113; D. Del. Case No. 21-01455, ECF No. 24.

5. Azurity and its predecessor Silvergate Pharmaceuticals, Inc. have brought at least a dozen cases in the District of Delaware concerning the alleged infringement of patents within the enalapril patent family. Among those cases are the First and Second Bionpharma Cases, as well as three other cases against Bionpharma that are now closed concerning members of the enalapril patent family other than the '023 patent and the '405 patent. *See*:

- D. Del. Case No. 18-01962, *Silvergate Pharms., Inc. v. Bionpharma Inc.* (closed case);
- D. Del. Case No. 19-00678, *Silvergate Pharms., Inc. v. Amneal Pharms. LLC* (closed case);
- D. Del. Case No. 19-01067, *Silvergate Pharms., Inc. v. Bionpharma Inc.* (closed case);

- D. Del. Case No. 19-02100, *Azurity Pharms., Inc. v. Alkem Labs. Ltd.* (active case);
- D. Del. Case No. 20-00753, *Azurity Pharms., Inc. v. Annora Pharma Priv. Ltd.* (closed case);
- D. Del. Case No. 20-01255, *Silvergate Pharms., Inc. v. Amneal Pharms. LLC* (closed case);
- D. Del. Case No. 20-01256, *Silvergate Pharms., Inc. v. Bionpharma Inc.* (closed case);
- D. Del. Case No. 21-00196, *Azurity Pharms., Inc. v. Annora Pharma Priv. Ltd.* (active case);
- D. Del. Case No. 21-01286, *Azurity Pharms., Inc. v. Bionpharma Inc.* (the First Bionpharma Case);
- D. Del. Case No. 21-01455, *Azurity Pharms., Inc. v. Bionpharma Inc.* (the Second Bionpharma Case);
- D. Del. Case No. 21-01522, *Azurity Pharms., Inc. v. CoreRx, Inc.* (closed case); and
- D. Del. Case No. 21-01707, *Azurity Pharms., Inc. v. Aurobindo Pharma Ltd.* (active case).

6. In October 2022, Azurity brought the current case that is before me against Novitium (Novitium Case), a Delaware corporation with a New Jersey principal place of business. (ECF No. 1 ¶ 3.)[1] The Novitium Case concerns a claim of:

> patent infringement of … the … '023 patent … and … the … '405 patent … aris[ing] out of Novitium's imminent manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do the foregoing within the United States of the product that is the subject of Bionpharma['s] … ANDA No. 212408 … prior to the expiration of the ['023 patent and the '405 patent].

(*Id.* ¶ 1.) Novitium will be the "contract manufacturer for Bionpharma's [generic enalapril] product." (ECF No. 8-1 p. 7; *see* ECF No. 1 ¶¶ 22, 23, 33, 34.)

[1] Novitium was acquired by ANI Pharmaceuticals, Inc., which is a Delaware corporation with a Minnesota principal place of business, in November 2021. (ECF No. 25 p. 12; ECF No. 27-2 p. 2; ECF No. 27-4 p. 2.)

7. Azurity admits in the complaint that the issue of whether Bionpharma's ANDA No. 212408 infringes the '023 patent and the '405 patent is being addressed in the First and Second Bionpharma Cases in the District of Delaware. (*See* ECF No. 1 ¶¶ 25, 27.) In addition, Azurity recognizes that the product that Novitium is set to manufacture (Novitium Formulation) for Bionpharma "is the same formulation as the previous formulation sold by Bionpharma and its previous manufacturer." (*Id.* ¶ 9.) Azurity further admits that "the Novitium Formulation is … the alleged infringing product at issue in [the First and Second Bionpharma Cases]." (*Id.*; *see id.* ¶¶ 25, 27 (acknowledging same).) Azurity's certification pursuant to Local Rule 11.2 acknowledges in relevant part that "[t]he matter in controversy is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding, *except* [the First and Second Bionpharma Cases]." (ECF No. 1 p. 12 (emphasis added).)

8. Novitium now moves to transfer the Novitium Case to the District of Delaware, so that the Novitium Case might be litigated in conjunction with the First and Second Bionpharma Cases and with the other cases related to the infringement of the enalapril patent family. (ECF No. 10.) Novitium argues that a transfer would avoid unnecessary duplication of effort and inconsistent rulings, in view of the ongoing litigation and previous decisions concerning: (a) the validity of the patents within the enalapril patent family; and (b) the marketing and sale of enalapril generic products. (ECF No. 10-1 pp. 16–18, 23.) In opposition, Azurity counters that "[a]lthough sometimes transferring one case to a district where related cases are pending can save judicial economy, there would be no such savings here," because "many of the factual issues that will be addressed here—including the acts of infringement—are distinct from the issues being litigated" in the First and Second Bionpharma Cases. (ECF No. 26 p. 8.)[2]

9. 28 U.S.C. § 1404 provides:

> For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought

[2] Azurity repeatedly refers to the litigation that concerns Bionpharma in the District of Delaware as "the Delaware Action." (*See generally* ECF No. 26.) In actuality, there are two active cases there, *i.e.*: (1) the First Bionpharma Case, which concerns the '023 patent and which was transferred from the District of New Jersey; and (2) the Second Bionpharma Case, which concerns the '405 patent and which is being managed in coordination with the First Bionpharma Case. As noted above, both cases remain designated as being open and active on the District of Delaware docket. *See* D. Del. Cases Nos. 21-01286, 21-01455.

> or to any district or division to which all parties have consented.

28 U.S.C. §1404(a).

10. A determination on the transfer of a case to another venue is not dispositive and is within a Magistrate Judge's authority. *See* 28 U.S.C. §636(b)(1)(A); Fed.R.Civ.P. 72(a). With that in mind, the standard that I must apply for determining whether to transfer a case to a different venue pursuant to Section 1404(a) is well-settled. *See Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879–80 (3d Cir. 1995) (setting forth the factors that can be considered); *see also In re Amendt*, 169 F.App'x 93, 96 (3d Cir. 2006) (reiterating the *Jumara* holding). A court possesses broad discretion to transfer an action to a federal district court where the action might have been brought. *See* 28 U.S.C. §1404(a); *see also Jumara*, 55 F.3d at 875, 877 n.3, 883. As to the potential effect upon the public interest in deciding whether to transfer a case to another venue, "there is no exhaustive list of public interest factors, and the analysis is flexible and individualized based on the unique facts of each case." *Fin. Res. Fed. Credit Union v. Alloya Corp. Fed. Credit Union*, No. 20-06180, 2021 WL 268176, at *7 (D.N.J. Jan. 27, 2021).

11. Given the unique facts present here, I will exercise my discretion to transfer the Novitium Case to the District of Delaware for the sake of the public interest. In view of the extensive previous and ongoing litigation concerning the enalapril patent family, it is apparent that the District of Delaware is better-suited to manage and resolve the Novitium Case.

12. The District of Delaware has conducted several bench trials in cases addressing the enalapril patent family, and that court has issued comprehensive opinions concerning whether certain patents have been infringed and other related issues as recently as January 2023. *See, e.g.*, *Silvergate Pharms., Inc. v. Bionpharma Inc.*, Nos. 18-01962, 19-01067, 2021 WL 1751148, at *1–36 (D. Del. Apr. 29, 2021) (issuing findings of fact and conclusions of law concerning infringement of several members of enalapril patent family after a five-day bench trial), *aff'd sub nom. Azurity Pharms., Inc. v. Bionpharma Inc.*, Nos. 21-01926, 21-01927, 2022 WL 703903 (Fed.Cir. Mar. 9, 2022); *see also Azurity Pharms., Inc. v. Bionpharma Inc.*, Nos. 21-01286, 21-01455, 2023 WL 157732, at *1–10 (D. Del. Jan. 11, 2023) (denying Azurity's motion to dismiss antitrust counterclaims in the First and Second Bionpharma Cases); *Azurity Pharms., Inc. v. Bionpharma Inc.*, Nos. 21-01286, 2023 WL 122292, at *1–5 (D. Del. Jan. 6, 2023) (denying Bionpharma's motion for a judgment on the pleadings in the First Bionpharma Case); *Azurity Pharms., Inc. v. Alkem Labs. Ltd.*, No. 19-02100, 2021 WL 5332406, at *1–8 (D. Del. Nov. 16, 2021) (issuing findings of fact and conclusions law concerning infringement of several members of enalapril patent family after

a claim construction hearing); *Silvergate Pharms., Inc. v. Amneal Pharms. LLC*, No. 19-00678, ECF Nos. 164–172 (transcripts of bench trial held in February 2021). The breadth of the District of Delaware's comprehensive familiarity with the issues surrounding the enalapril patent family cannot be overlooked.

13. The duplication of judicial oversight that could ensue due to the overlap between the Novitium Case and the First and Second Bionpharma Cases is apparent upon a review of Azurity's own submissions. Azurity admits that fact discovery is proceeding and a trial date has been tentatively set for February 2024 in the First and Second Bionpharma Cases. (ECF No. 25 pp. 7, 15; *see* ECF No. 27-5 pp. 4, 19 (scheduling order issued by District of Delaware in the First and Second Bionpharma Cases).) As part of the discovery process in the First and Second Bionpharma Cases, Azurity served extensive discovery demands in 2022 on Bionpharma concerning Novitium's involvement with the contract to manufacture the Novitium Formulation, such as: (a) documents and communications between Bionpharma and Novitium; (b) Novitium's responsibilities for the alleged conduct in the First and Second Bionpharma Cases; (c) all documents provided by Bionpharma to Novitium discussing enalapril and Azurity; and (d) information showing all units of the Novitium Formulation manufactured by Novitium for Bionpharma. (*See* ECF No. 35 pp. 11, 12; *see also* ECF Nos. 35-3, 35-4 (Azurity's document and deposition demands concerning Novitium's interactions with Bionpharma).) Having already had the benefit of culling through discovery concerning Novitium in the oversight of the First and Second Bionpharma Cases, the transferee court will already be more than familiar with the duplicative discovery that will be provided in the Novitium Case.

14. When litigation is proceeding in one district court concerning the infringement of several patents in the same patent family, the transfer of a case from another district court is favored when that case involves: (a) a patent that is part of or derived from that same patent family; (b) the same or related parties; and (c) the same complex issues that have been addressed in motion practice, discovery, claim construction opinions, and trials by the Judges of the transferee court. *See LifeCell Corp. v. LifeNet Health*, No. 15-06701, 2016 WL 544489, at *3 (D.N.J. Feb. 9, 2016) (transferring case concerning alleged infringement of patent for soft tissue grafts used in regenerating skin). As to the Novitium Case, it would "not seem practical to have two different District Judges dedicate the resources necessary to address the same complicated patent issues," and thus a "transfer [would] promote[] the goal[s] of federal patent uniformity" and "judicial economy." *Id.*

15. The Novitium Case also does not present a true local controversy that would tend to favor retaining it in the District of New Jersey. Even though

Novitium is based in New Jersey, pharmaceutical patent litigation does not constitute a local controversy, as such cases "are matters of national concern that are not local controversies, nor do they implicate the public policies of any one forum." *Teva Pharms. USA, Inc. v. Sandoz Inc.*, No. 17-00275, 2017 WL 2269979, at *8 (D.N.J. May 23, 2017) (internal quotation marks and citations omitted); *see Bayer Pharma AG v. Watson Labs. Inc.*, No. 14-01804, 2014 WL 2516412, at *10 (D.N.J. June 2, 2014) (stating same).

16. It would be inequitable to require Novitium, which just recently entered into a contract with Bionpharma to produce the Novitium Formulation, to defend this case in the District of New Jersey. Indeed, Bionpharma indicates that it will be responsible for any liability incurred by Novitium due to the relationship with Bionpharma in the Novitium Case. (ECF No. 8-1 pp. 7, 11 (Bionpharma advising the Court that it seeks "to dispel the cloud of litigation that threatens its manufacturing and supplier relationships, such as with Novitium," as "Bionpharma is the real party-in-interest here").) In view of Bionpharma's statements, Azurity's argument that "Bionpharma's other purported interest as a litigant in a pending action against Azurity is likewise insufficient because Bionpharma will not be bound by the results of this action" is without merit. (ECF No. 25 p. 8.)

17. Therefore, the key interest at stake in the Transfer Motion — *i.e.*, the "practical considerations that could make the trial easy, expeditious, or inexpensive" — weighs in favor of Novitium's request to transfer. *Jumara*, 55 F.3d at 879. "[J]udicial efficiency is precisely the sort of practical consideration that is vital to a transfer analysis." *Bayer Pharma AG*, 2014 WL 2516412, at *9. "[T]he possibility of incongruous construction of the patents" should be avoided at all costs. *COA Network, Inc. v. J2 Glob. Commc'ns, Inc.*, No. 09-06505, 2010 WL 2539692, at *5 (D.N.J. June 17, 2010); *see Bayer Pharma AG*, 2014 WL 2516412, at *8 (transferring the pharmaceutical patent infringement case because cases that were pending in another district were "sufficiently similar," and holding that "the legal claims and issues involved need not be identical" to favor a transfer).

18. The holding in *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17-07106, 2018 WL 4089031 (D.N.J. Aug. 27. 2018), wherein Judge Kevin McNulty declined to transfer a pharmaceutical patent infringement case concerning Suboxone, is instructive. In that case, the allegedly infringing generic defendants sought to transfer the case to the District of Delaware, as a District Judge there had previously addressed cases concerning a different member of the Suboxone patent family, but not the particular patent in issue in the New Jersey case. Judge McNulty held that the patent at issue in the District of New Jersey case was "non-identical" to the patents being addressed in the District of Delaware. *Id.* at *4.

In stark contrast, the two members of the enalapril patent family raised by Azurity in the Novitium Case, *i.e.*, the '023 patent and the '405 patent (*see* ECF No. 1 ¶ 1), are precisely the same patents that are currently at issue in the First and Second Bionpharma Cases. *See* D. Del. Case No. 21-01286, ECF No. 89 (amended complaint concerning alleged infringement of the '023 patent); D. Del. Case No. 21-01455, ECF No. 1 (complaint concerning alleged infringement of the '405 patent).) As a result, "it is difficult to imagine a more extravagantly wasteful and useless duplication of time and effort than for multiple suits involving the same product[s] and the [same] patent[s], instituted within the past several months, to proceed in different districts." *Teva Pharms. USA, Inc.*, 2017 WL 2269979, at *9 (internal quotation marks, alterations, and citations omitted) (transferring a pharmaceutical patent infringement case to district court currently presiding over several other cases concerning the same patent).

19. Azurity asserts that the District Judge currently presiding over the First Bionpharma Case, the Second Bionpharma Case, and other active cases concerning the enalapril patent family, *i.e.*, Judge Mitchell S. Goldberg, was only recently assigned upon the elevation to the Third Circuit Court of Appeals of the previous District Judge, *i.e.*, Judge Leonard P. Stark. Azurity argues that as a result of this new assignment, the proposed transferee court will not be as completely familiar with those matters as might be assumed at first glance. (ECF No. 26 p. 25.)

20. Azurity's argument, however, ignores what is easily revealed upon a review of the related District of Delaware dockets, which are replete with examples of Judge Goldberg having been actively involved in case management and addressing several substantive issues in those cases for almost one year. *See, e.g.*, D. Del. Case No. 21-01455, ECF No. 72 (transcript of status hearing held April 25, 2022); *id.* ECF No. 99 (transcript of discovery hearing held September 14, 2022); *id.* ECF No. 151 (transcript of status hearing held November 30, 2022); *id.* ECF Nos. 158, 159 (opinion and order addressing motion to dismiss in January 2023); D. Del. Case No. 21-01286, ECF Nos. 253, 254 (opinion and order addressing motion for judgment on the pleadings in January 2023); D. Del. Case No. 21-00196, ECF No. 169 (order addressing discovery dispute in January 2023); D. Del. Case No. 19-02100, ECF Nos. 147, 158 (orders issued in May and June 2022 concerning disputes over expert opinions on the issue of invalidity, which included descriptions of the patent and generic formulations). In addition, a review of all of the dockets related to the cases for the enalapril patent family reveals that Magistrate Judge Christopher J. Burke has been assigned to those cases throughout their history. *See, e.g.*, D. Del. Case No. 19-02100, ECF No. 178 (order dated July 11, 2022 issued by Judge Burke concerning discovery dispute); D. Del. Case No. 21-01286, ECF No. 126 (order dated January 27, 2022 assigning case to Judge Burke); D. Del. Case No. 21-1455, ECF No. 37 (same).

Thus, the institutional memory for all of those cases remains preserved in the transferee court.

21. In acknowledging that a transfer of the Novitium Case could be a distinct possibility, Azurity requests that "the Court should order that Bionpharma and Novitium cannot seek consolidation of this action with the [First and Second Bionpharma Cases], or otherwise use transfer to delay Azurity's trial against Bionpharma," reasoning that "[s]uch a condition would also minimize the burden on the District of Delaware from transfer by preventing interference with its existing schedule." (ECF No. 26 pp. 9, 30, 31.) As a Judge in the District of New Jersey, I have no intention of interfering with the management of another district court's docket. *See G.G. v. Cigna Health & Life Ins. Co.*, No. 22-00078, 2022 WL 2657252, at *1 (D. Utah July 8, 2022) (declining to enter an order binding a transferee court that "potentially interferes with that court's preferred schedule regarding filings"). The request is denied.

22. Despite ordering this case to be transferred to the District of Delaware, the parties are advised that:

> The Clerk shall take no action with respect to a Magistrate Judge's order for transfer of venue … until 14 days from the filing of such an order. In the event that a notice of appeal from such an order is filed within the time allowed in the Rule, the Clerk shall take no action until the appeal is decided by the [District] Judge.

L.Civ.R. 72.1(c)(1)(C). [3]

Accordingly,

[3] As I am deciding the Transfer Motion pursuant to Section 1404(a), it is unnecessary to address any of Novitium's arguments concerning the reach of Section 1400(b) or the preclusive effect of Judge Shipp's transfer order from the First Bionpharma Case. (*See* ECF No. 10-1, pp. 16–20; ECF No. 35, pp. 9, 10.)

IT IS on this **20th** day of **January 2023** **ORDERED** that:

1. The Transfer Motion is resolved as follows: (a) **GRANTED** to the extent that the Transfer Motion is filed on Novitium's behalf seeking a transfer of this case; and (b) **ADMINISTRATIVELY TERMINATED** without prejudice to the extent that the Transfer Motion raises other relief.

2. The Intervene Motion is **ADMINISTRATIVELY TERMINATED** without prejudice, with leave for such relief to be sought upon the transfer of this case, if appropriate.

3. This case will be **TRANSFERRED** to the United States District Court for the District of Delaware, wherein the Clerk of that Court shall be notified that this case is related to D. Del. Case Nos. 21-01286 and 21-01455.

4. The Clerk of the Court is directed to terminate ECF Nos. 8 and 10.

5. The Clerk of the Court will take no action on the transfer of this case for 14 days from the entry of this Opinion and Order pursuant to Local Civil Rule 72.1(c)(1)(C).

/s/ Edward S. Kiel
EDWARD S. KIEL
UNITED STATES MAGISTRATE JUDGE